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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,551	12/08/2003	Todd K. Whitehurst	AB-308U	4571

23845 7590 05/18/2006

ADVANCED BIONICS CORPORATION
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/731,551	WHITEHURST ET AL	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification did not disclose the use of inhibitory stimulation or sensing any change in sympathetic firing and adjusting the stimulation in response to the sensed signal, both in combination with the stimulation of intercostal nerves or branches. The original specification only described the use of excitatory stimulation of intercostal nerves (page 15) and the use of sensing sympathetic firing with sympathetic stimulation (page 21). This rejection is related to new matter from the amendment of 7/27/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Bardy (5334221).

Bardy discloses the use of fat pad stimulation (abstract and throughout the specification) to treat angina (title and throughout the specification).

Claims 9, 11, 13-18, 20, 21, and 28 are rejected under 35 U.S.C. 102(a) as being anticipated by Hill et al (WO 02/34330 A2). Hill discloses the use of his system for angina (e.g. page 3, line 19) and the stimulation of the nerves located “in the pectoral region of the left chest located beneath the fascia on the muscle and motor point of the pectoral muscle with stimulation of the musculocutaneous and thoracic nerves” (page 4, line 8) and shows and describes the use of stimulating the nerves in the chest wall/ribs at the T2 and T3 levels in figure 1B (page 8) and therefore stimulates the intercostal nerves and/or an intercostal nerve branch since Hill stimulates the ventral branch of thoracic nerves as seen and described in Hill’s specification. In addition, Hill discloses the use of sensors for internal or external control of the stimulation (pages 4 and 14 and table II), the use of an external programmer to program the stimulator with pulse parameters (pages 12, 14, etc), and the excitatory stimulation (page 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-8, 19, and 24-27 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hill et al. Most of the claim limitations are addressed above in the 102 rejection. In addition, Hill states that the IMD can have the electrodes carried on the surface of the implantable device (page 8, lines 28-30) and are therefore leadless stimulators that will require the stimulator(s) to be placed adjacent the nerves and/or between the ribs.

In the alternative, Hill discloses the claimed invention using electrodes on the surface of the IMD and stimulating the T2 and T3 levels except for the leadless stimulator capable of being placed adjacent the nerves and/or between the ribs and being two or more stimulators. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surface electrodes system and method as taught by Hill, with the leadless stimulator capable of being placed adjacent the nerves and/or between the ribs and the system using two or more stimulators to stimulate the nerves since it was known in the art that: leadless stimulators are used to place the stimulator adjacent nerves and or locations such as between the ribs to stimulate the particular nerves to provide a stimulator that only requires minimally invasive insertion/surgery of the stimulator to stimulate the appropriate nerves for therapy for the patient; and that more than one stimulator can be used to allow the stimulators to treat different areas of the body, such as different nerves, without multiple leads or a large IMD and that can provide different independent pulses to the different areas.

Claims 3, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill et al. Hill discloses the claimed invention providing stimulation to the nerves through a lead and electrode (figure 1C) and using the sensor to adjust the pulse parameters (pages 5 and 12) to provide the appropriate pulses for therapy, but does not disclose the pulses using less than 15 mA and the lead being up to about 150 mm long. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system and method as taught by Hill with the pulses using less than 15 mA and the lead being up to about 150 mm long, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the nerve stimulation system and method as taught by Hill, with the pulses using less than 15 mA and the lead being up to about 150 mm long since it was known in the art that nerve stimulation systems and method use pulses using less than 15 mA and the lead being up to about 150 mm long to provide a therapeutic pulse to the patient without causing pain to the patient and a lead with the ability to locate the electrode at several places along the nerve to find the appropriate place to stimulate without snaking the lead throughout the body or requiring the extra length to be accommodated.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

The examiner is requiring the Applicant to state on the record, in response to this detailed action, what nerves the applicant considers the intercostal nerve branches to consist of.

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Specifically, the names of the nerves (such as the lateral cutaneous branch, anterior cutaneous branch, etc), whether these branches are directly connected to the intercostal nerves, and whether they are connected toward or away from the spine. This information is required to extend the domain of search for prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

5/15/06

GRE
May 15, 2006